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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,705	03/17/2006	Yoshitaka Tomigahara	2006_0367A	5356
513	7590	05/06/2010	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P.			ANDERSON, REBECCA L	
1030 15th Street, N.W.,			ART UNIT	PAPER NUMBER
Suite 400 East			1626	
Washington, DC 20005-1503				
NOTIFICATION DATE		DELIVERY MODE		
05/06/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com  
coa@wenderoth.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/572,705	TOMIGAHARA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	REBECCA L. ANDERSON	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 January 2010.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 4-14, 17-22, 25, 26, 28, 30, 31, 34, 35, 37 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) 4-14, 19-22, 25, 26, 28, 30, 31, 34, 35, 37 and 39-43 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 17 is/are rejected.
- 7) Claim(s) 17 and 18 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Claims 4-14, 17-22, 25, 26, 28, 30, 31, 34, 35, 37 and 39-43 are currently pending in the instant application. Claims 4-14, 19-22, 25, 26, 28, 30, 31, 34, 35, 37 and 39-43 are withdrawn from consideration as being for non-elected subject matter. Claim 17 is rejected. Claims 17 and 18 are objected. Applicants' amendment to claims 17 and 18 filed 28 January 2010 has overcome the objection to these claims for ending with a period. While applicants' amendment has overcome the previous 35 USC 102(b) rejection, since applicants' instant claim 17 is currently rejected under 35 USC 102(b), the objection to claims 17 and 18 as containing non-elected subject matter is maintained.

### ***Election/Restrictions***

Applicants' amendment filed 28 January 2010 has amended claims 34, 37 and 39 from composition claims to method of use claims. Additionally, the amendment adds new claim 43 which is also a method of use claim. Therefore, claims 34, 37, 39 and 43 are considered withdrawn claims as they now fall within withdrawn group IX:

Group IX      Claims 34, 35, 37, 39, 40 and 43 drawn to methods of use of 2H-pyridinone compositions.

As per MPEP 803.02, the examiner will determine whether the entire scope of the claims is patentable. The examiner has previously indicated that Applicants' elected species is considered allowable. Therefore, according to MPEP 803.02:

Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable \*\*, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected

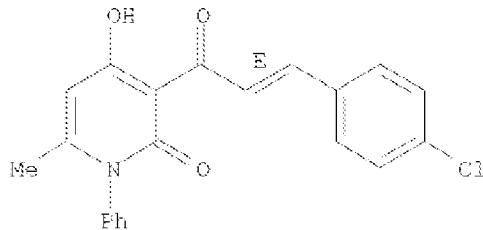
species held withdrawn from further consideration.

the elected species shall be rejected, and claims to the nonelected species will be held withdrawn from further consideration.

As the elected species has been found allowable, the search and examination had been previously extended to include the compound:

RN 16862-54-7 CAPLUS  
CN 2(1H)-Pyridone, 3-(p-chlorocinnamoyl)-4-hydroxy-6-methyl-1-phenyl-, (E)- (8CI) (CA INDEX NAME)

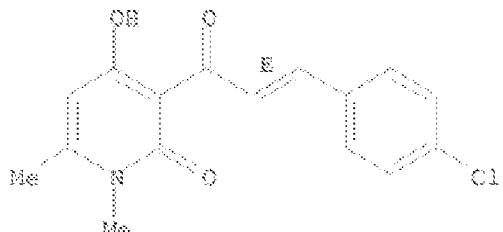
Double bond geometry as shown.



, which was not found allowable. Applicants' amendment filed 28 January 2010 has cancelled claims 1-3, 15 and 16 and amended claims 34, 37 and 39 to be withdrawn method claims, which are dependent upon claim 17, which has overcome the 35 USC 102(b) rejection of these claims as being anticipated by Vul'fson (abstract). Therefore, the search and examination has now been extended to include the compound:

RN 16862-48-9 CAPLUS  
CN 2(1H)-Pyridone, 3-(p-chlorocinnamoyl)-4-hydroxy-1,6-dimethyl-, (E)- (8CI) (CA INDEX NAME)

Double bond geometry as shown.

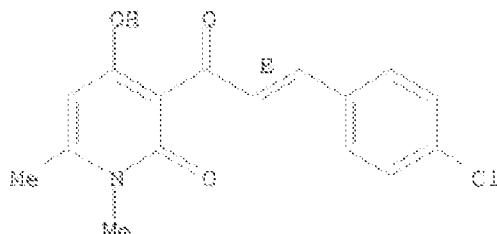


which is not allowable.

**Claims 17 and 18 have been examined to the extent that they are readable on the elected embodiment, the elected species of example 3a-32 and the additional species of the compound of:**

RN 16862-48-9 CAPLUS  
CN 2-(1H)-Pyridone, 3-(p-chlorocinnamoyl)-4-hydroxy-1,6-dimethyl-, (E)- (SCI)  
(CA INDEX NAME)

Double bond geometry as shown.



. Since the elected embodiment is not allowable, subject matter not embraced by the elected embodiment is therefore withdrawn from further consideration. Claims 4-14, 19-22, 25, 26, 28, 30, 31, 34, 35, 37 and 39-43 are therefore withdrawn from consideration as being for non-elected subject matter. It has been determined that the entire scope claimed is not patentable.

### ***Claim Objections***

Claims 17 and 18 are objected to as containing non-elected subject matter. Claims 17 and 18 presented drawn solely to the elected embodiment identified supra would overcome this objection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

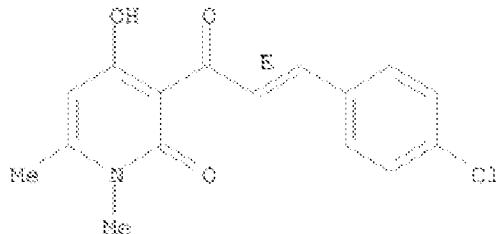
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Vul'fson (abstract).

Vul'fson discloses the compound, for example, of formula IV wherein R is Me and R1 is p-Cl, specifically:

NN 16962-48-9 CASRN  
CN 2(1H)-Pyridone, 3-(p-chlorocinnamoyl)-4-hydroxy-1,6-dimethyl-, (E)- (8CI)  
(CA INDEX NAME)

Double bond geometry as shown.



which corresponds to the 2(1H)-pyridinone composition as claimed in claim 17 , for example, wherein rII is H; rII' is methyl; k is 1; and XIII is chlorine. The compound in the Vul'fson reference corresponds to the composition of claim 17 as the preparation of formula IV wherein R is Me and R1 is p-Cl was in piperidine or in 10% aqueous NaOH and MeOH. Methanol corresponds to the inert carrier (defined in the instant specification to include pharmaceutically acceptable carriers) in the composition claim.

In regards to the inert carrier, as can be seen by Schubert et al. (previously disclosed on a PTO-892) methanol is considered a pharmaceutically acceptable organic solvent, see page 125 which states that the method uses pharmaceutically acceptable organic solvents and page 126 which discloses methanol as a solvent.

### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/  
Primary Examiner, AU 1626*

3 May 2010

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Rebecca Anderson  
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